REMARKS

Claims 1-23 are all the claims pending in the application; claims 5-19 and 21-23 are withdrawn from consideration; claims 1-4 and 20 are rejected.

After entry of this amendment, claims 5-19 and 21-23 will be canceled, and claims 1-4 and 20 will be pending in the application.

The specification has been amended to insert sequence identifiers.

Claims 1-4 and 20 have been amended to more clearly state that which Applicants regard as their invention, and to place the claims more fully in U.S. format.

Support for the replacement of the phrase "functional region" with "apoptosis-inducing domain" may be found at the bottom of page 3, where it is discussed that the function domain of the Fas antigen is the region essential for signal transduction of apoptosis.

Applicants have also amended the Sequence Listing to include the amino acid sequence of the human (SEQ ID NO:22) and mouse (SEQ ID NO:23) Fas antigens, and the specification to include the corresponding sequence identifiers. The full-length sequence of both polypeptides is disclosed in the two publications cited in the instant specification (human Fas antigen: page 3, line 12, *Cell* 66, 223 (1991); mouse Fas antigen: page 4, line 1, *J. Immunology* 148, 1274 (1992)). This amendment will allow a person reading the specification and claims to refer to the amino acid sequences of both antigens when reference is made to particular amino acids and particular domains of the antigens (*see, e.g.*, page 3, lines 13-18, and claims 2-4).

No new matter has been added. Entry of the Amendment is respectfully requested.

I. Formal Matters

A. Applicants thank the Examiner for returning an initialed and signed copy of the Form PTO 1449 submitted to the Patent Office on August 24, 2000.

However, Applicants note that the Examiner has not yet returned an acknowledged copy of the Form PTO 1449 submitted with the application papers on December 23, 1999. Applicants therefore respectfully request return of an appropriately acknowledged copy of this form (enclosed herewith for the Examiner's convenience) with the next paper from the Patent Office.

B. On the Office Action summary sheet the Examiner acknowledges that a copy of the priority document was received from the International Bureau. However, the Examiner does not acknowledge Applicants' claim for foreign priority, made in the letter to the commissioner dated December 23, 1999. Applicants respectfully request the Examiner to acknowledge Applicants' claim for foreign priority in the next paper from the Patent Office.

Applicants also note that while the Examiner acknowledges Applicants' claim for domestic priority under 35 U.S.C. §§120 and/or 121 on the Office Action summary sheet, Applicants have not made a claim for domestic priority.

II. Election/Restrictions

In view of the Restriction/Election requirement, Applicants have canceled the non-elected claims 5-19 and 21-23 without prejudice or disclaimer.

III. Specification

At page 2 of the Office Action, the Examiner states that claim 3 fails to further limit the subject matter of claim 2 because claim 3 recites a broader scope of subject matter (a portion of

the mouse Fas antigen plus a signal sequence) than the scope of claim 2 (a portion of the mouse Fas antigen).

In response, Applicants include herewith an amendment to claim 3 such that it now depends only depend from claim 1. In addition, claim 3 has been amended to incorporate the recitation of the size of the partial Fas antigen of claim 2 into claim 3. In view of the amendments, Applicants assert that claim 3 is a proper dependent claim, further limiting the subject of the claim from which it depends, and Applicants therefore respectfully request reconsideration and withdrawal of this objection.

IV. Rejection of Claims Under 35 U.S.C. §112

At page 2 of the Office Action, claims 1-4 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

A. The Examiner asserts that claim 1 recites "a functional region of an Fas antigen" but it is not clear what the metes and bounds are for the phrase. The Examiner suggests that it may mean the death domain of the protein, as discussed in Takebayashi et al. (1996).

In response, Applicants note that the specification discusses the functional region of the Fas antigen at page 3, beginning at line 19. Therein it is stated that "the region essential for the signal transduction of apoptosis" is the functional region. In addition, as pointed out by the Examiner, this region has been termed the "death domain" by at least one group.

Thus, Applicants assert that the functional region is defined in the specification, i.e. as an apoptosis-inducing domain. Applicants have amended claims 1-3 to recite "the apoptosis-inducing domain" in place of "the functional domain," thereby more clearly defining that which Applicants regard as their invention.

In view of the amendment to the claims, Applicants assert that the claims are definite as written, and therefore respectfully request reconsideration and withdrawal of this rejection.

B. The Examiner states that claim 3 recites "the signal peptide region" but it is not clear what the metes and bounds are for this phrase. The Examiner explains that while the specification states that page 3, lines 13-14, that amino acids 1-16 of human Fas are "assumed to be the signal peptide", the specification does not define that is "the signal peptide region" of mouse Fas antigen.

In response, Applicants note that the specification discloses both a "signal peptide" and a larger "signal peptide region" for both human and mouse Fas antigen. Claims 3 and 4, as amended, recite the "signal peptide region." The signal peptide region for both human and mouse Fas antigen is described at page 11, lines 2-5. Therein it is stated that the human Fas antigen signal peptide region is from –16 to 23 of SEQ ID NO:22, and the mouse Fas antigen signal peptide region is from –21 to 14 of SEQ ID NO:23.

As the metes and bounds of the claims are thus clearly set forth in the specification, Applicants assert that the rejected claim is definite as written, and therefore respectfully request reconsideration and withdrawal of this rejection.

C. The Examiner asserts that while claim 4 recites "the -21^{st} to 14^{th} positions of mouse Fas", it is not clear what the metes and bounds are for the phrase. The Examiner explains that the specification does not define the amino acid position as a signal peptide sequence.

In response, Applicants refer to the comments above concerning the identity of the signal peptide region recited in the rejected claim, and the location of support in the specification for

the signal peptide region. Claim 4 has also been amended to more clearly state that it is the "signal peptide region" that is being recited in the claim.

As the metes and bounds of the claim are thus clearly set forth in the specification, and the claim has been amended to more clearly recite the invention being claimed, Applicants assert that the rejected claim is definite as written, and therefore respectfully request reconsideration and withdrawal of this rejection.

D. At page 3 of the Office Action, claim 20 is rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

At pages 3-5, the Examiner sets forth a number of reasons why a claim to a therapeutic treatment for a cancer or autoimmune disease is not enabled. The Examiner concludes that the specification provides insufficient guidance, and provides no working examples of a treatment *in vivo* which would provide guidance to one skilled in the art to use the claimed invention without undue experimentation, and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed invention with a reasonable expectation of success. The Examiner concludes by stating that considering the lack of examples and the limited teachings of the specification, and the unpredictability in the art, undue experimentation would be required to practice the claimed invention.

In response, Applicants have amended claim 20 to delete reference to a "therapeutic agent." The claims now simply recites a composition comprising the plasmid DNA and a DNA molecule encoding an effector protein. As the composition is clearly enabled for an *in vitro* use, there is no issue of enablement.

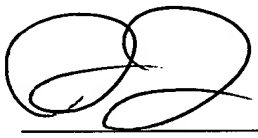
In view of the amendment to the claim, Applicants assert that the claim is enabled and respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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